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Assessment of Causes of Adverse Drug Reaction Underreporting in South of Iraq

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Abstract: Background: Pharmacy professionals, other healthcare professionals, and patients can all gain from a continuous adverse drug reaction tracking and reporting strategy. The purpose of pharmacovigilance procedures is to collect information on various aspects of the safety of pharmaceutical goods in general. Patient, healthcare professional, and manufacturer reports are the main sources of information on adverse events that arise spontaneously. Pharmacovigilance is a requirement for all healthcare practitioners, making pharmacists and doctors essential healthcare providers in responsibility of adverse drug reaction reporting throughout their practices and teaching the general public about pharmacovigilance. The current study sought to investigate and evaluate the main causes of ADR underreporting.

Methodology: Doctors, clinical pharmacists, and general pharmacists in the Basra governorate made up the study's sample. A total of (552) of the (900) healthcare providers who were the target of the study took part. Doctors made up 268 of the total participants (552), general pharmacists made up 225, and clinical pharmacists made up 59. This study, conducted in the Basra Governorate, covered 8 significant hospitals. A paper questionnaire was used in a randomly chosen observational cross-sectional study. All data were examined using IBM SPSS Statistic version 26.

Results: In terms of the overall participant count, there were significantly more females (65.6%) than males

(34.4%). Statistics show that the proportion of HCPs with fewer than five years of work experience (64.6%) is higher than that of those with five or more years of experience (35.4%).

Lack of clinical expertise among healthcare professionals was the major reason of underreporting.

Conclusion: The most significant causes contributing to the fall in the degree of documentation or underreporting in health institutions are the absence of clinical expertise for the majority of health staff and the failure to get information from patients in an appropriate, correct, and precise way.

Key words: Doctors, clinical pharmacists, and general pharmacists.

1. Introduction

When humanity developed, systems developed with it in all area of life, and medical sciences in general, and pharmaceutical sciences in particular, were not excluded from what happened, so societies and special centers or organizations have been establishes in this regard. Among those organizations, the most important of which nowadays is the World Health Organization (WHO). WHO has taken care of many medical matters, including what we talked about, which is the appearance of some unwanted symptoms when using certain treatments to treat disease conditions. This organization define an adverse drug reaction (ADR) which until now is used, is “a response to a drug that is noxious and unintended and occurs at doses normally used in man for the prophylaxis, diagnosis or therapy of disease, or for modification of physiological function”.(1) The European Medicines Agency (EMA) has a similar definition for it that is: "A response to a medicinal product which is noxious".(2)

Adverse medication responses are a frequent, sometimes avoidable source of disease, disability, and even death. They rank sixth among all causes of mortality and account for between 5 and 10% of hospital expenses. They cause between 3% and 6% of hospital admissions at any age and up to 24% in the older population(3).

Speaking of the adverse drug reaction, over the past years, it is clear that ADRs are one of the most important causes of death all over the world. Generally, they affect 10% of outpatients, 5-10% of hospital stays, and 10-20% of hospitalized patients, increasing their overall stay(4). Estimates in the United States of America indicate that generally adverse drug reactions are the fourth to sixth largest cause of death(5). Up to 10% of patients in European hospitals have an ADR during their stay, and 3.6% of all hospital admissions in Europe are attributed to ADRs. Additionally, less than 0.5% of hospitalizations are likely to result in a fatal ADR(6). Also, in Europe, and specifically in Italy, some studies indicate that 6.2% of hospitalization cases are due to adverse drug reactions of medicines(7).

If we look at the Asian continent and take India as an example, we will see that 5% of hospitalized patients were exposed to adverse drug reactions(8).

Underreporting of negative incidents is a key issue with any spontaneous reporting system. According to estimates, only 2% to 4% of non-severe responses and seldom more than 10% of significant adverse drug reactions (ADRs) are reported to the British spontaneous reporting program(9). A comparable estimate states that less than 1% of suspected significant ADRs are reported directly to the FDA. This implies that the instances included in any surveillance program's numerator that are reported voluntarily typically only reflect a tiny part of the total number of incidents that have actually happened. If submitted reports, regardless of quantity, are of excellent quality, the effect of underreporting can be partly mitigated(10).

Over time, all of the nation's participating in the WHO Program for International Drug Monitoring have come to consensus on the meanings of a few key pharmacovigilance words(11). The term "pharmacovigilance," which was first used in France, has likely gained international traction in the past ten years as the most commonly used way to refer to "the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other possible drug-related problems." The International Conference of Harmonization (ICH) of Technical Requirements for Registration of Pharmaceuticals for Human Use endorsed this definition when it was released by the WHO in 2002 (12).

The Iraqi Pharmacovigilance Centre, was formed by the MOH in 2010 and joined WHO-UMC. Numerous pharmacovigilance actions, including ADR reporting and the release of various brochures and guidelines, have been carried out since the inception of this center.(13)

Published in 2012, the "Guidelines for the National Pharmacovigilance System in Iraq" are aimed at medical professionals.(13)The Iraqi Pharmacovigilance Center has created a variety of rules based on the EU GVP, Arab GVP standards, and certain internal circulars. Pharmaceutical businesses are required to disclose both major and non-serious ADRs in compliance with the aforementioned circulars. Additionally, the center's rules mandate reporting of both domestic and international cases, however the reporting deadlines for international cases are a little different from those in other regions.(13)

All healthcare professionals must participate in pharmacovigilance, making pharmacists and doctors crucial healthcare professionals in charge of pharmacovigilance and ADR reporting throughout their practices as well as educating the general public about pharmacovigilance. According to investigations, a significant under-reporting is caused by healthcare professionals' attitudes, a lack of understanding, and a need for awareness regarding reporting ADR.(14,15) Pharmacy students, according to Gavaza and Bui, had good intentions and a favorable attitude toward reporting adverse drug reactions (ADRs), but they lacked the understanding of how to report major ADRs(16). Initiatives for ongoing education are required for doctors, nurses, and pharmacists. According to Hajebi et al., it is critical to provide ongoing ADR-related learning programs up until a point at which nursing staff members' voluntary recording of ADRs becomes customary and habitual.

The goal of the current study was to evaluate the causes of ADR underreporting among physicians and pharmacists in Basra.

2.Methodology

2.1 Population

Population of this study were doctors, clinical and general pharmacists in Basra governorate.

2.2 Sample size

Totally, from (900) healthcare providers were targeted, (552) of them participated in the study. From the total number of participants (552), (268) were doctors, (225) were general pharmacists and (59) were clinical pharmacists (figure 1). The sample size or the numbers of participants in this study that was calculated by G power software to create statistical significancy was (80-120) as a minimum.

2.3 Criteria of the sample

2.3.1 Inclusion criteria

The selection of the study participants was subjected to the following specifications:

1- Basra healthcare providers (physicians, pharmacists and clinical pharmacists)

2- Both male and female HCPs

3- Participants with at least 6 months of work experience in Basra hospitals.

4- regarding the specialties of doctors, all of them were included except psychiatrists and anesthesiologists.

2.3.2 Exclusion criteria

1- HCPs who refuse to enter this study.

2- Psychiatrists, anesthesiologists, nurses and pharmacist assistances.

3- HCPs with work experience duration less than of 6 months.

4- Participants work outside from the Basra governorate.

2.4 Study setting

This study done at Basra governorate and include 8 important hospitals:

Al-Basra teaching (Al-Jomhuri) hospital, Al-Sadr teaching hospital, Al-Fayhaa general hospital, Al-Mawani general hospital, Basra Obstetrics and Gynecology (Ibn-Ghazwan) hospital, Al-Zubair general hospital, Children's Specialty (Al-Tefl) hospital and Cardiac center. Basra is one of Iraqi cities located the far south of the country on the west bank of the Shatt al-Arab, and is the administrative and political center of Basra Governorate.

2.5 Study design

A randomly selected observational cross-sectional study was performed using a paper questionnaire to evaluate and assess the causes of ADR underreporting among the Basra physicians, general and clinical pharmacists. Our study took advantage of a period of ten months, specifically from March to December of the year 2022.

2.6 Questionnaire

The paper questionnaire consists of 11 statements.

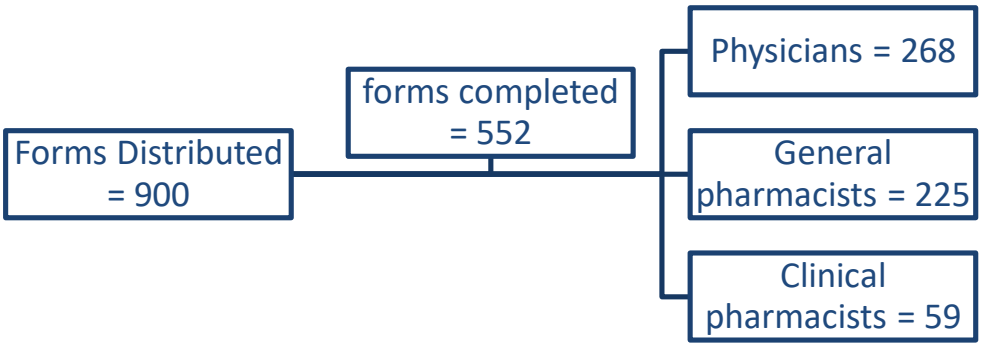

Figure 1. Demonstration of the sample size

2.7 Statistical Analysis

By using IBM SPSS Statistic version 26, all data was analyzed. Answers were represented as frequency (N) as well as percentage (%).

All data was assessed in term of physicians, general and clinical pharmacists' responses to get comparison between them in evaluation of the common causes of underreporting of adverse drug reaction.

The study of each participant's answer as well as other participant-related factors were conducted using a chi-squared test. P value less than 0.05 was deemed significant.

3. Results

The demographic data of the HCPs who took part in the trial, including doctors, general and clinical pharmacists, is shown in Table 1.

From the total number of participants, female was significantly higher percentage (65.6%) than male (34.4%). Also statistically, the percentage of HCPs with less than 5 years' work experience (64.6%) exceeds those with 5 years or more of experience (35.4%). Concerning distribution of participants according to the age, individuals in the age range (25-34 years) made up significantly higher percentage (47.3%) of the total. Al-Basra teaching (Al-Jomhuri) hospital and Al-Sadr teaching hospital had significantly the more percentage of participants, (20.1%) and (19.4%) respectively.

Table 1 Demographic information from healthcare practitioners' responses to a questionnaire. Data are expressed as N & %, for a total of 552 participants.

≤ 5 years			

P value < 0.05 considered significant

Eleven statements had been prepared for evaluating of the ADR underreporting causes. Except for the first statement, all of the responses of HCPs were significantly different among them (table 2).

Table 2 Comparing of physician, general, and clinical pharmacist replies to several questions concerning practice of pharmacovigilance (causes of ADRs underreporting). Data are expressed as N & %, for a total of 552 participants.

1.As a cause of underreporting: It is challenging to determine whether an ADR happened due to a lack of clinical information.				
2. As a cause of underreporting: Uncertain or possible relationship between the medication and the negative outcome				
3. As a cause of underreporting: the ADR is unimportant to document				
4. As a cause of underreporting: fear that a report may result in additional work				
5. As a cause of underreporting: The required ADR reporting form is not accessible.				
6. As a cause of underreporting: not enough details provided by the patient				

7. As a cause of underreporting: insufficient time to complete a report				
8. As a cause of underreporting: not being aware that there is a nationwide ADR reporting system.				
9. As a cause of underreporting: knew nothing about reporting				
10. As a cause of underreporting: do not feel obligated to disclose well known adverse medication reactions.				
11. As a cause of underreporting: Considering that you are not responsible				

P value < 0.05 considered significant

4. Discussion

Before discussing the results of this study, it is worth mentioning that the results of this research were taken from participants with different years of experience, as well as those who work in the eight most important hospitals in Basra Governorate to ensure results closer to reality.

Healthcare providers under-reporting of ADRs is a concern in several nations, including Iraq. Lack of awareness and expertise of methods to recognize and report ADRs might be used to explain this. Table 8 include the most important factors that lead to the lack of adverse drug reaction reporting. The most factor result in ADRs underreporting phenomenon is: “it is challenging to determine whether an ADR has occurred due to a lack of clinical information” (87.7%). In Baghdad in 2016, results nearby to what appeared in our study appeared, as about 68% of the physicians said they lacked the necessary clinical expertise to identify ADRs (17). In Erbil over one-third of the pharmacists stated that they lack the clinical expertise needed to identify ADRs (18).

Insufficiency of patients’ feedback is another effective factor (80.1%). This factor is very important especially in our society, the point that all the previous studies performed in Iraq did not took it as one of the ADRs underreporting barriers. Most of the patients admitted in our health units have low social education and do not cooperate with the medical staff or the ADRs reporter in explaining their condition properly.

Another factor was the unknown relationship between the medicine and an ADR (77.2%). This factor also refers us to the lack in proper and important clinical perception of the healthcare providers.

Absence of ADR forms when we want them is also another challenge (71.8%). The absence of the reporting form was highlighted by over three-quarters of respondents (71.6%) in Baghdad at 2016 and this result was very similar to the result of this study (19).

The next cause of underreporting of the ADRs was that the ADR was not worth to report (68.4%). This may be due to healthcare providers thinking that an ADR is common or not serious, so no need to document it. This conclusion is supported by the fact that more than 90% of doctors in Iraq believe that only ADRs that result in hospitalization, life-threatening diseases, congenital anomalies, permanent impairment, or incapacity should be reported (17).

Another important reason for underreporting is deficiency in knowledge about the adverse drug reaction mechanism (65.3%). Similar result achieved in Basra at 2016 as (68.1%) of participants mention that they do not have sufficient knowledge about the steps of pharmacovigilance and adverse drug reaction documentation (20).

Conclusion

With regard to the reasons that lead to the lack of documentation of adverse drug reactions, the result of this study showed that the lack of clinical knowledge for the most health personnel and the failure to take information from patients in an adequate, correct and accurate manner, are the most important factors leading to the decline in the level of documentation or underreporting in health institutions.

Recommendation

Continuing and developing the process of teaching ADRs reporting, starting from the Ministry of Higher Education and Scientific Research, modifying the curriculum and updating the educational system (taking advantage of smart applications and social media is very useful in this field) in this regard, ending with the Iraqi Ministry of Health and health institutions through the maintenance and development of courses and workshops dedicated to increasing the scientific level of the healthcare providers.

Obliging pharmaceutical companies operating in the Iraqi market through the Pharmacists Syndicate or the Ministry of Health to hold educational workshops on how to practice pharmacovigilance and obliging pharmacists and physicians in the private sector to fill out special forms, is a very necessary element in developing the experience of the drug monitoring in our beloved country. Especially that pharmaceutical companies, accurately brand companies, have very extensive experience in this field.

One of the important things in improving the experience of filling out forms is the use of modern methods, such as using smart applications or simplifying the paper forms, which allow enough time for the notary to write down the necessary requirements for the pharmacovigilance process.

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